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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an *in vivo* Anti-CD19 Chimeric Antigen Receptor (CAR) for the Treatment of CD19-Expressing Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Capstan Therapeutics (Capstan), located in San Diego, California, the United States of America.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before **[INSERT DATE 15 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]** will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-6467; E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application 62/006,313 (HHS Reference E-042-2014-0-US-01), filed 2 June 2014; PCT Application PCT/US2015/033473 (HHS Reference E-042-2014-0-PCT-02), filed 1 June 2015; Australian Patent 2015270912

(HHS Reference E-042-2014-0-AU-03), issued 17 December 2020; Canadian Patent Application 2951045 (HHS Reference E-042-2014-0-CA-04), filed 1 June 2015; Chinese Patent 201580033802.5 (HHS Reference E-042-2014-0-CN-05), issued 31 August 2021; European Patent 3149044 (HHS Reference E-042-2014-0-EP-06), issued 21 October 2020 and validated in Germany (HHS Reference E-042-2014-0-DE-19), Spain (HHS Reference E-042-2014-0-ES-20), France (HHS Reference E-042-2014-0-FR-21), The United Kingdom (HHS Reference E-042-2014-0-GB-22), Italy (HHS Reference E-042-2014-0-IT-23), and Ireland (HHS Reference E-042-2014-0-IE-24); Israeli Patent 249305 (HHS Reference E-042-2014-0-IL-07), issued 1 October 2021; Indian Patent Application 201647041047 (HHS Reference E-042-2014-0-IN-08), filed 1 June 2015; Japanese Patent 6797693 (HHS Reference E-042-2014-0-JP-09), issued 20 November 2020; South Korean Patent Application 2016-7036828 (HHS Reference E-042-2014-0-KR-10), filed 1 June 2015; Mexican Patent 383150 (HHS Reference E-042-2014-0-MX-11), issued 3 June 2021; New Zealand Patent Application 727167 (HHS Reference E-042-2014-0-NZ-12), filed 1 June 2015; Saudi Arabian Patent 8651 (HHS Reference E-042-2014-0-SA-13), issued 15 September 2021; Singapore Patent 11201609960Q (HHS Reference E-042-2014-0-SG-14), issued 28 September 2021; United States Patent 10,287,350 (HHS Reference E-042-2014-0-US-15), issued 14 May 2019; Hong Kong Patent HK 1234420 (HHS Reference E-042-2014-0-HK-16), issued 4 June 2021; United States Patent 11,236,161 (HHS Reference E-042-2014-0-US-17), issued 1 Februry 2022; New Zealand Patent Application 764530 (HHS Reference E-042-2014-0-NZ-18), filed 19 May 2020; European Patent Application 20197459.9 (HHS Reference E-042-2014-0-EP-25), filed 22 September 2020; Australian Patent Application 2020267211 (HHS Reference E-042-2014-0-AU-26), filed 11 November 2020; Japanese Patent 7004470 (HHS Reference E-042-2014-0-JP-27), issued 6 January 2022; Mexican Patent Application MX/a/2021/006239 (HHS Reference E-042-2014-0-MX-28), filed 27 May 2021; Israeli

Patent Application 283423 (HHS Reference E-042-2014-0-IL-29), filed 25 May 2021; Hong Kong Patent Application 42021038427.7 (HHS Reference E-042-2014-0-HK-30), filed 8 September 2021; United States Patent Application 17/557,845 (HHS Reference E-042-2014-0-US-31), filed 21 December 2021; Japanese Patent Application 2021-215427 (HHS Reference E-042-2014-0-JP-32), filed 29 December 2021; United States Patent Application 17/696,249 (HHS Reference E-042-2014-0-US-33), filed 16 March 2022; Israeli Patent Application 291292 (HHS Reference E-042-2014-0-IL-34), filed 13 March 2022, and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The license to be granted may be worldwide, and may be limited to the following field of use:

"The commercial development, production, and sale of a monospecific chimeric antigen receptor (CAR)-based immunotherapy using T lymphocytes transfected *in vivo* using non-viral, synthetic nanoparticle-based systems comprised of lipids, polymers and/or lipopolymers that deliver a nucleic acid cargo that expresses an anti-CD19 CAR having:

1) the CDR polypeptide sequences of the anti-CD19 antibody known as Hu19; and

2) a T cell signaling domain;

for the treatment or prevention of CD19-expressing cancers.

The Licensed Field of Use explicitly excludes the development of a bispecific or bicistronic CAR and the use of viral-based nucleic acid systems or vectors to express the CAR."

CD19 is a cell surface protein that is expressed on a number of types of cancer cells, including various lymphomas and leukemias. Although there are several therapies available for patients with these types of cancers, many pateints still either do not respond to these therapies or experience disease relapse and require additional lines of therapy. As a result, there continues to be an unmet patient need. The development of a new anti-

CD19 CAR-based therapy can potentially meet some or all of these needs. As a result, the development of a new therapeutic option targeting CD19-expressing cancers will benefit public health by providing an effective treatment for patients that might otherwise have no options.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: July 21, 2022.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

[FR Doc. 2022-16056 Filed: 7/26/2022 8:45 am; Publication Date: 7/27/2022]